

REMARKS

This paper is submitted in response to the restriction requirement the Office mailed on February 11, 2005. Provision for extension of time accompanies this paper.

5 After entry of the amendments, claims 1-10 and 23-31 are pending. The new claims add no new matter. Support for treating osteoporosis and bone fractures conditions is, e.g., at paragraphs 319 and 320. Support for the chemical structures is, e.g., at paragraphs 156-161, 202-204, 363 and 364. The elected species compound, $3\alpha,17\beta$ -dihydroxy-19-norandrost-4-ene, is compound 1.1.5.2
10 as described, e.g., in groups 9 and 37 at paragraphs 166 and 202.

Restriction and election

The Office required selection of a single clinical treatment method and a single chemical species and disclosed in the specification. To respond to the
15 requirement, Applicants hereby elect the subject matter of new claim 28, which claims a single compound $3\alpha,17\beta$ -dihydroxy-19-norandrost-4-ene for treating osteoporosis. Applicants believe that the requirement to select a single species and a single clinical condition is met by new claim 28.

At paragraph 5, The Office stated that six different groups of chemical
20 structures could be identified. However, on review of those groups at pages 5 and 6 of the office action it became apparent that the Office was describing chemical structures that are not present in this application. For example, group 1 refers to fentanyl as the parent compound, although the compounds recited in this application do not include fentanyl. Similarly, variable groups such as R' and
25 X were not present in the claims that the Office reviewed. To facilitate prosecution, Applicants have altered the scope of the compounds to set forth a proposed group of compounds for purposes of complying with the restriction requirement. The base steroid structure in the new claims has been altered to eliminate variable groups R⁵, R⁷ and R⁸, which were present in the claims the
30 Office reviewed for the restriction and the proposed scope for the R⁶ variable group is -H or optionally substituted alkyl. In the claims the Office reviewed for

the restriction, R⁶ was defined as -H only. Also, as described below, Applicants have selected a single compound and treatment of osteoporosis for examination.

As suggested by the Office at paragraph 5 of the restriction requirement, Applicants have reduced the scope of the compounds that new independent claim 29 recites and they propose setting forth the scope of compounds that original claims 1-10 and new claims 23-31 now recite. Variable groups R⁵, R⁷ and R⁸ are absent from the scope of the new claim set. The clinical conditions that are listed in claim 29 are also reduced to treating innate immune suppression conditions. The new claims are more easily searched and Applicants request the Office to consider treating the subject matter that claim 29 recites as a single invention for purposes of examination and to consider the sufficiency of the written description in the disclosure for the new claims.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 501536.

Respectfully submitted,

Hollis-Eden Pharmaceuticals, Inc.

Date: 6-10-05

By: Daryl D Muenchau

Daryl D. Muenchau, Reg. No. 36,616
Hollis-Eden Pharmaceuticals, Inc.
4435 Eastgate Mall, Suite 400
San Diego, CA 92121
P: 858-320-2569
F: 858-558-6470